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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/057,928	01/29/2002	David Segev	01/21646	3760
7590 05/27/2005			EXAMINER	
G.E. EHRLICH (1995) LTD.			RILEY, JEZIA	
c/o ANTHONY CASTORINA SUITE 207			ART UNIT	PAPER NUMBER
2001 JEFFERSON DAVIS HIGHWAY ARLINGTON, VA 22202			1637	
			DATE MAILED: 05/27/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	10/057,928	SEGEV, DAVID	
Office Action Summary	Examiner	Art Unit	
•	Jezia Riley	1637	
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address	
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	ely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).	
Status			
1)⊠ Responsive to communication(s) filed on <u>07 Mar</u> 2a)□ This action is <b>FINAL</b> . 2b)⊠ This     3)□ Since this application is in condition for alloward closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro		
Disposition of Claims			
<ul> <li>4)  Claim(s) 1-93 is/are pending in the application.</li> <li>4a) Of the above claim(s) 40-88 is/are withdraw</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-39 and 89-93 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) 1-93 are subject to restriction and/or expressions.</li> </ul>	n from consideration.		
Application Papers			
<ul> <li>9) The specification is objected to by the Examine 10) The drawing(s) filed on 29 January 2002 is/are: Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examine 10. </li> </ul>	a) accepted or b) dobjected or b) dobjected drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119		•	
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Application ity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage	
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/17/02.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:		

#### **DETAILED ACTION**

1. Applicant's election of Group I and species election in the reply filed on 7/14/04 and 3/7/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 2, 4, 6-10, 12, 14-17, 19, 21-25, 27, 29-39, 89-93 read on elected species. After searching said elected, species, the examination of the instant application has been extended to include all possible species. Therefore Claims 1-39 and 89-93 have been examined and claims 40-87 have been withdrawn.

### **Drawings**

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figure 1a and 1b are not formal drawings. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

# Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is vague and indefinite because it is unclear of what are the metes and bounds fore the term "derivatives thereof". This term can encompass a large number of possible compounds in organic chemistry.

# Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-39 and 89-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compound as shown in Figure 10 (v), does not reasonably provide enablement for compounds as broadly claim in instant claim 1. Claim 1 is a compound comprising a backbone bearing a plurality of ligands and said ligands include at least one pair of adjacent ligands linked via a linker. And said compounds can be used in pharmaceutical composition as an active ingredient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses several examples of how to prepare some specific compounds. Additionally, there is no guidance as how one of ordinary skill in art will select a specific compounds from the one as broadly claimed in

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claim 1 for example, as an active ingredient in a pharmaceutical composition. One skilled in the art would recognize that the efficacy of an oligomeric analog or mimic for these uses depends critically on its having suitable conformation and flexibility, and also of its ability to penetrate cell membranes; and it is highly unpredictable whether a given oligonucleotide or mimic structure will permit binding to the target with high specificity and affinity. The efficacy of oligo analogs as hybridizing therapeutic agents depends unpredictably on the structures of the oligos. Uhlmann et al. (Chem. Reviews, 1990, 90, pp.544-584) state that modified, nuclease-resistant oligos often have lower affinities for their target sequences than do natural DNA or RNA oligos (page 562, right col., 2nd paragraph; page 564, first full paragraph), that modified oligos may not penetrate cells as well as unmodified oligos (Page 568), and may fail to be taken up and transported into the target cells in amount capable of delivering a therapeutic benefits (page 567). In view of the breadth of the claims, which encompass an immense number of oligo mimic compounds of unknown activity; given that it is impossible to predict which of the multitude of oligo mimic structures encompassed by the claims would be able to bind successfully to a complementary nucleic acid or to protein with high affinity and specificity; and given the lack of guidance in the specification regarding how to select which of the specific oligos mimic structures encompassed by the claims could be made and used with a reasonable expectation of success, undue experimentation is required to make and use the invention as broadly claimed.

### 7. No claim is allowed.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, May 26, 2005

PRIMARY EXAMINER